

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PHT CORPORATION,)	
)	
Plaintiff,)	
v.)	Civil Case No. 04-60 GMS
)	
INVIVODATA, INC.,)	
)	
Defendant.)	

PHT CORPORATION,)	
)	
Plaintiff,)	Civil Case No. 04-61 GMS
v.)	
)	
CRF, INC.,)	
)	
Defendant.)	

PHT CORPORATION,)	
)	
Plaintiff,)	
v.)	Civil Case No. 04-821 GMS
)	
ETRIALS WORLDWIDE, INC.,)	
)	
Defendant.)	

PHT'S OPENING BRIEF ON CLAIM CONSTRUCTION

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PHT'S OPENING BRIEF ON CLAIM CONSTRUCTION

Pursuant to the Court's order, Plaintiff PHT Corporation ("PHT") provides its opening brief on claim construction issues for claim terms in dispute between the parties. Based on the prior exchanges of preliminary claim construction charts, a subsequent meet-and-confer session on claim construction issues, and the submission of a joint claim chart, PHT believes there are 10 terms in dispute between the parties.¹

These claim construction issues are susceptible of resolution based on a plain reading of the claim language, patent specification, and prosecution history. Resort to extrinsic evidence is not necessary. The intrinsic evidence amply supports PHT's proposed constructions.

I. OVERVIEW OF THE TECHNOLOGY OF THE '985 PATENT

The patent-in-suit, U.S. Patent No. 6,095,985 ("the '985 patent"), (J.A. Ex. A), pertains to portable devices and systems that measure and record, or measure, or record the state of a patient's perceived health and transmit that data to a centralized location. The breakthrough embodied in the claims of the '985 patent is the ability to transmit data recorded on the portable device directly to a central database, without the need for additional processing of the data. Thus, unlike prior art systems, the data from the portable device is not downloaded onto a local computer for later transmission to a central database. Instead, the data is transmitted from the portable device to the centralized database through one or more networks capable of transmitting data.

¹ PHT reserves the right to address additional disputed issues of claim construction that may emerge through simultaneous briefing on claim construction issues ordered by the Court.

In the claims at issue in this litigation, the portable devices are referred to as data loggers or personal health trackers. Data loggers have now become commercially known as electronic patient diaries (“EPD’s”). EPD’s are used by patients in clinical trials to record information relevant to the trial. Because the EPD’s are portable -- and usually handheld -- patients and doctors involved in the trial may take them anywhere, such as to work, or to where a doctor involved in the trial interviews patients. This feature allows data to be input into the EPD in a timely, accurate manner, regardless of where the patient is at the time the data is to be recorded. Among the types of data that can be input into an EPD are symptom intensity (*e.g.*, the level of pain experienced by the patient), the times at which the patient took any drugs to combat pain or to alleviate other symptoms, the amount of medication taken, and any side effects felt by the patient.

After being recorded by the patient in the EPD, the data can then be transmitted directly to a remote data storage location, such as a central server. The data is not processed by or accessed on an intervening computer.

II. PROCEDURAL BACKGROUND

PHT filed actions against invivodata, Inc. (“invivodata”) and CRF, Inc. (“CRF”) on January 28, 2004, alleging that each company infringes the ’985 patent. In their Answers, invivodata and CRF denied infringement and asserted that the ’985 patent is invalid and unenforceable. On July 6, 2004, PHT filed an action against etrials Worldwide, Inc. (“etrials”), also alleging infringement of the ’985 patent. Etrials in its Answer denied infringement and asserted that the ’985 patent is invalid.

On January 14, 2005, the Court ordered a consolidated process for claim interpretation for each of the cases. Pursuant to the Court’s January 14th order, the

parties exchanged lists of claim terms believed to be in dispute with their proposed constructions of those terms; this exchange was followed by a telephonic meet-and-confer session in which the parties discussed issues of claim construction and areas that remained in dispute. On February 18th, the parties submitted a final joint claim chart to the Court. The Court has directed simultaneous briefing on these claim construction issues, with opening briefs due on March 11th and answering briefs on April 1st. A *Markman* claim construction hearing before the Court is scheduled for April 19, 2005, at 9:00 a.m.

III. GOVERNING LEGAL STANDARDS

The fundamental rules governing the Court's construction of patent claims are well established. Claim construction is a matter of law for the Court. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979 (Fed. Cir. 1995) (*en banc*), *aff'd*, 517 U.S. 370 (1996); *Scriptgen Pharms., Inc. v. 3-Dimensional Pharms., Inc.*, 79 F. Supp. 2d 409, 411 (D. Del. 1999). That is, the Court determines the meaning of pertinent claim language to establish the scope of the patent's claims for purposes of determining questions of infringement and validity. *Markman*, 52 F.3d at 978-79. It is well settled that, in construing patent claims, the Court should look first to intrinsic evidence, beginning with the language of the claims themselves. *Vitronics Corp. v. Conceptoronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996); *Scriptgen Pharms.*, 79 F. Supp. 2d at 411. The Court also looks at the specification and may consider the prosecution history of the patent, if in evidence. *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed. Cir. 2002); *see also Vitronics*, 90 F.3d at 1582.

Claim terms are to be given their ordinary and customary meaning, unless the patent specification clearly establishes the inventors' intent to convey a special meaning. *Vitronics*, 90 F.3d at 1582; *Tate Access Floors, Inc. v. Interface Architectural Res., Inc.*, 279 F.3d 1357, 1370 (Fed. Cir. 2002). "The terms used in the claims bear a 'heavy presumption' that they mean what they say and have the ordinary meaning that would be attributed to those words by persons skilled in the relevant art." *Tex. Digital Sys., Inc. v. Telegenix, Inc.*, 308 F.3d 1193, 1202 (Fed. Cir. 2002); *accord Johnson Worldwide Assocs., Inc. v. Zebco Corp.*, 175 F.3d 985, 989 (Fed. Cir. 1999). The meaning of any technical term used in the patent claims is to be construed based on the understanding a person of ordinary skill in the field of the invention. *Nystrom v. Trex Co.*, 374 F.3d 1105, 1111 (Fed. Cir. 2004); *Scriptgen Pharms.*, 79 F. Supp. 2d at 414.

A court therefore will interpret claim language in favor of the ordinary meaning of a term during claim construction, unless a patentee has chosen "to be his own lexicographer" and has used "terms in a manner other than their ordinary meaning" in either the patent specification or file history. *Vitronics*, 90 F.3d at 1582; *see also Scriptgen Pharms.*, 79 F. Supp. 2d at 415-16. To that end, a court must "review the specification to determine whether the inventor has used any terms in a manner inconsistent with their ordinary meaning." *Vitronics*, 90 F.3d at 1582. "The specification acts as a dictionary when it expressly defines terms used in the claims or when it defines terms by implication. . . . Thus, the specification is always highly relevant to the claim construction analysis." *Id.* at 1582; *see also Liquid Dynamics Corp. v. Vaughan Co.*, 355 F.3d 1361, 1367 (Fed. Cir. 2004). Any special meaning of a term must be stated clearly

and unambiguously in the specification and may not be pieced together based on a group of ambiguous references. *See Vitronics*, 90 F.3d at 1582; *Markman*, 52 F.3d at 980.

If the patentee did not act as a lexicographer, the Court will presume that the claim terms “mean what they say, and, unless otherwise compelled, give full effect to the ordinary and accustomed meaning” of those terms. *Johnson Worldwide*, 175 F.3d at 989. The presumption that the claim term has its ordinary and accustomed meaning may be rebutted “if the inventor has disavowed or disclaimed scope of coverage, by using words or expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope.” *Tex. Digital*, 308 F.3d at 1204.

When the specification “makes clear that the invention does not include a particular feature, that feature is deemed to be outside the reach of the claims of the patent, even though the language of the claims, read without reference to the specification, might be considered broad enough to encompass the feature in question.” A patentee may also limit the scope of the claims by disclaiming a particular interpretation during prosecution.

Microsoft Corp. v. Multi-Tech Sys., Inc., 357 F.3d 1340, 1347 (Fed. Cir. 2004) (citation omitted) (quoting *SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc.*, 242 F.3d 1337, 1341 (Fed. Cir. 2001)); *see also Vitronics*, 90 F.3d at 1582; *Southwall Techs., Inc., v. Cardinal IG Co.*, 54 F.3d 1570, 1576 (Fed. Cir. 1995). There can be no such disclaimer “unless the patentee has demonstrated a clear intention to limit the claim scope using ‘words or expressions of manifest exclusion or restriction.’” *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004) (quoting *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1327 (Fed. Cir. 2002)).

The Court may also consider the prosecution history of the patent, if in evidence, in determining whether the patentee has acted as a lexicographer. *CCS Fitness*, 288 F.3d at 1366; *see also Vitronics*, 90 F.3d at 1582.

Absent a disclaimer or lexicography by the patentee, the specification and prosecution history cannot be used to enlarge, diminish, or vary the limitations in the claims. *Markman*, 52 F.3d at 980. In undertaking claim construction, the Court may not rewrite the claim terms by importing language from the specification or the prosecution history, either to expand or to limit the scope provided by their otherwise unambiguous meaning. *See id.*; *Tex. Digital*, 308 F.3d at 1204-05; *Key Pharmaceuticals, Inc. v. Hercon Labs. Corp.*, 981 F. Supp. 299, 309 (D. Del. 1997). Thus, the Court's construction must give effect to what the inventors actually claimed through the words they chose in their claims. *Chef America, Inc. v. Lamb-Weston, Inc.*, 358 F.3d 1371, 1374 (Fed. Cir. 2004); *Tate Access Floors*, 279 F.3d at 1370.²

IV. PROPOSED CLAIM CONSTRUCTIONS

There appear to be 10 disputed issues of claim construction in relation to the presently asserted claims of the '985 patent. As for the remaining terms in claims 22-

² In most situations, review of the intrinsic evidence regarding a claim will resolve any ambiguity in a disputed claim term. In such circumstances, it is improper to rely on extrinsic evidence, such as expert testimony. *See Vitronics*, 90 F.3d at 1583; *see also Pickholtz v. Rainbow Techs., Inc.*, 284 F.3d 1365, 1372-73 (Fed. Cir. 2002); *Scriptgen Pharms.*, 79 F. Supp. 2d at 411. Only if the meaning of a term remains ambiguous after a review of this intrinsic evidence may the Court consider extrinsic evidence of the likely meaning of the term to one of ordinary skill in the art. *Vitronics*, 90 F.3d at 1583-84; *Scriptgen Pharms.*, 79 F. Supp. 2d at 411. Indeed, the Federal Circuit has emphasized that "[i]n those cases where the public record unambiguously describes the scope of the patented invention, reliance on any extrinsic evidence is improper." *Vitronics*, 90 F.3d at 1583.

30, 34, and 36-41, no construction of the terms is necessary. Defendants have *not* offered proposed constructions for these terms. The constructions of these terms are not in dispute, and the Court should adopt PHT's proposed interpretations, as set forth in the parties' Joint Claim Chart. (D.I. 32 (04-60); D.I. 30 (04-61); D.I. 24 (04-821).)

Each of the terms in dispute is addressed below.

1. "Subjective Data"

Claim 22 of the '985 patent contains the following limitation: "a data logger that collects and records *subjective data from a subject regarding the subject's psychological condition and subjectively observed physiological condition.*" (Col. 30, ll. 14-17, emphasis added.) Claim 34 contains the same limitation: "a portable unit having a data logger that collects and records *subjective data from a subject regarding the subject's psychological condition and subjectively observed physiological condition.*" (Col. 31, ll. 17-20, emphasis added.) The phrase "subjective data from a subject regarding the subject's psychological condition and subjectively observed physiological condition" in claims 22 and 34 should be construed as "data input by the patient regarding the patient's psychological condition and subjectively observed physiological condition." In other words, the term "subjective data," as used in the claims of the '985 patent, means "data input by the patient."

With respect to the term "subjective data," the patentees acted as their own lexicographers, defining the term in the specification. The patentees plainly ascribed a meaning other than its ordinary meaning as the specification makes clear. *Vitronics*, 90 F.3d at 1582; *see also Scriptgen Pharms.*, 79 F. Supp. 2d at 415-16; *Liquid Dynamics Corp.*, 355 F.3d at 1367.

The specification of the '985 patent states:

the term “subjective” data will refer to that data which is input by the patient to the data logger 106, regardless of whether that data pertains to the patient or the patient’s environment, and whether or not the information is objective or factual, such as medication dosage or consumption of a particular food. (Col. 5, ll. 40-45, emphasis added.)

Thus, the specification explicitly defines “subjective data” to include any data entered by the patient in the data logger, whether subjective or objective, such as data regarding the patient’s intake of food or medicine.

Although the definition of “subjective data” provided in the specification is very broad -- encompassing data pertaining to the patient’s environment -- both claims 22 and 34 provide an additional limitation on the type of “subjective data” that can be entered into the data logger. The plain language of both claims requires the subjective data to be data “regarding the subject’s psychological condition and subjectively observed physiological condition.” (Col. 30, ll. 15-17; Col. 31, ll. 17-20.) Therefore, with respect to claims 22 and 34, the “subjective data” that is collected includes objective or factual data relating to the subject’s self-perceived psychological condition and subjectively observed physiological condition.³

CRF and invivodata, by contrast, attempt improperly to read a limitation from the specification into the claims. The proposed construction offered by invivodata

³ Other non-asserted claims of the '985 patent do not limit “subjective data” to data “regarding the subject’s psychological condition and subjectively observed physiological condition.” Claim 14 of the '985 patent and the claims that depend from it claim a method of tracking a medical subject’s state of health comprising the step of “collecting subjective data from the subject with a subjective data logger.” (Col. 29, ll. 42-43.) Unlike claims 22 and 34, these claims include no limit on the type of subjective data that can be collected from the subject.

and CRF,⁴ which includes data input by the subject regarding “the subject’s environment,” ignores the plain language of claims 22 and 34, which includes no mention of the “subject’s environment.” It is hornbook law that “it is improper to read a limitation from the specification into the claims.” *Liebel-Flarsheim Co.*, 358 F.3d at 904; *see also, e.g., Teleflex*, 299 F.3d at 1326 (“[L]imitations from the specification are not to be read into the claims.”); *Scriptgen Pharms.*, 79 F. Supp. 2d at 416. CRF and invivodata’s construction should be rejected and the Court should adopt PHT’s proposed construction.

2. **“Data Transmission Device Capable of Connecting Directly to a Communication Network”**

Claim 22 contains the following language:

a data transmission device ***capable of connecting directly to a communication network*** to allow transmission of data to a destination site from points of access to the network that are remote to the destination site. (Col. 30, ll. 24-27, emphasis added.)

The construction of the phrase “capable of connecting directly to a communications network” is in dispute.⁵ The specification and prosecution history of the ’985 patent make clear that “capable of connecting directly” means that the data transmission device is capable of transmitting data from the data logger to a communication network site without the data being processed by or accessed on an

⁴ Etrials asserts that it is unnecessary to construe the term “subjective data,” but does not oppose the construction offered by invivodata and CRF.

⁵ PHT proposes that this limitation of claim 22 be construed as “a component enabling connection of the data storage unit to a communications network, such as a telephone network, the Internet, a LAN, or a WAN, to permit transmission of data to a destination site from a point remote to the destination site without the data being processed by or accessed on an intervening computer.”

intervening computer. In contrast, defendants assert that “capable of connecting directly” excludes a system in which a modem is located between the data logger and the communication network. Defendants are wrong.

The '985 patent generally describes the invention as including “a communications system by which the data is periodically uploaded from the monitors to the database.” (Col. 1, ll. 63-65.) The specification further states:

Each health tracker includes a means for periodically uploading the collected data to the database. In the preferred embodiment, the health trackers communicate with the database via a public information network. (Col. 2, ll. 38-41.)

Thus, the patent describes a component of the device -- a means for periodically uploading data -- that enables uploading of data from the device to the database via a communications network, preferably a public information network. Claim 22 does not exclude the possibility of an intervening device, such as an external modem, between the health tracker and the database. In fact, the preferred embodiment expressly includes an external modem. In the preferred embodiment, the subjective data logger “connects to a **modem 110**.” (Col. 5, ll. 4-8, emphasis added.) The specification goes on to state:

In the preferred embodiment an external modem is used primarily because of lower cost, however those skilled in the art will recognize that it would also be possible . . . to plug a PCMCIA modem into the data logger 106. The external modem of the preferred embodiment also includes a chargepad for recharging the batteries of the portable monitor 108 and data logger 106 units. (Col. 5, ll. 8-15, emphasis added.)

The patent further explains that “the patient connects the data logger **106** to *modem 110* or another data transfer device which transfers the data to the database **102**

using a known data transfer protocol.” (Col. 26, ll. 35-37, emphasis added.) It could not be clearer that the preferred embodiment of the invention uses an external modem.

If defendants’ proposed construction were adopted, however, the claim would not cover the preferred embodiment. Defendant’s approach is sharply at odds with Federal Circuit case law. “A claim interpretation that excludes a preferred embodiment from the scope of the claim ‘is rarely, if ever, correct.’” *Globetrotter Software, Inc. v. Elan Computer Group, Inc.*, 362 F.3d 1367, 1381 (Fed. Cir. 2004) (quoting *Vitronics*, 90 F.3d at 1583).

Nor does the prosecution history require a different interpretation, as defendants will apparently contend. During the prosecution, the applicants described claim 41 of the application⁶ as “limited to a single, handheld unit having a data transmission device that connects directly to a communication network.” (Amendment of March 1, 1999 (J.A. Ex. C) at 13.) In distinguishing their invention from U.S. Patent No. 5,128,552 to Fang (which had been cited as prior art against the application) patentees made very clear that an EPD “*may* have a modem that is simply plugged into a telephone jack.” (J.A. Ex. C at 11, emphasis added.) Applicants further explained that the patented invention excludes a “secondary *control* unit,” such as a personal computer located between the handheld unit and the communication network. (*Id.*, emphasis added.) Applicants also explained that the handheld unit must have an on-board communication device, such as a telecommunications driver, that “invokes the transmission protocol of the unit, which includes dialing the number of the destination site, establishing a

⁶ Claim 41 ultimately issued as claim 22 in the ’985 patent.

connection and transmitting the data.” (*Id.*) And according to the applicants, such an onboard communications device does not necessarily *require* an internal modem: it “may have [such] a modem.” (J.A. Ex. C at 11.)

Nothing in the prosecution history excludes a system using an external modem, together with an on-board communication device such as a telecommunications driver, from the scope of the claims.

The statements by the applicants during prosecution do not begin to rise to the level of disclaimer of an external modem. There can be no such disclaimer “unless the patentee has demonstrated a clear intention to limit the claim scope using ‘words or expressions of manifest exclusion or restriction.’” *Liebel-Flarsheim*, 358 F.3d at 906 (quoting *Teleflex*, 299 F.3d at 1327). Applicants’ statements made during the prosecution -- *e.g.*, “*may* have an [internal] modem” -- do not amount to “words or expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope,” as is required for a disclaimer. *Tex. Digital*, 308 F.3d at 1204. Applicants merely explained that their claims excluded systems which required an external “secondary control unit” between the handheld unit and the communication network; they did not disclaim systems which used a “dumb” modem device that is controlled by the handheld unit, such as the external modem of their preferred embodiment.

Accordingly, defendants’ effort to interpret the claim to exclude the preferred embodiment should be rejected. The Court should construe this limitation of claim 22 as “a component enabling connection of the data storage unit to a communications network, such as a telephone network, the Internet, a LAN, or a WAN,

to permit transmission of data to a destination site from a point remote to the destination site without the data being processed by or accessed on an intervening computer.”

3. “Single, Unified, Portable Unit”

Claim 22 of the '985 patent contains the following limitation: “wherein each of the components of the health tracker is part of a single, unified portable unit that may be used by an ambulatory patient.” (Col. 30, ll. 27-30.) PHT proposes that this limitation be construed as “wherein the health tracker’s components are combined into a unit which is capable of being carried by a patient,” such as is described in the patent as the preferred embodiment. Defendants’ proposed construction apparently seeks to exclude the preferred embodiment which, as discussed above, includes the use of an external modem in combination with a telecommunications driver.

A data logger with an external modem constitutes a single, unified, portable unit when the external modem is combined with the health tracker into a single unit which itself is capable of being carried by a patient. That is, when a data logger is slipped into a cradle modem, the combined unit is a single, unified portable unit. Because the data logger/external modem configuration is, as discussed above, the preferred embodiment, defendants’ proposed interpretation might have the effect of excluding the preferred embodiment from the scope of the claim. Such an interpretation “is rarely, if ever, correct.” *Globetrotter*, 362 F.3d at 1381.

Accordingly, this limitation of claim 22 should be construed as “wherein the health tracker’s components are combined into a unit which is capable of being carried by a patient.” Defendant’s proposed construction, which seeks to exclude the preferred embodiment, should be rejected.

4. **“Digitized Representation of Writing”**

Claim 29 of the '985 patent recites: “A portable personal health tracker according to claim 22 further comprising a tactile input device on which the subject may write and the subject’s writing is detected, said tactile input device generating *a digitized representation of the detected writing*.” (Col. 30, ll. 49-53, emphasis added.) Claim 30 recites: “A portable personal health tracker according to claim 29 wherein *the digitized representation of the subject’s writing* is transmittable via the data transmission device.” (Col. 30, ll. 54-56, emphasis added.) PHT proposes that the term “digitized representation of . . . writing” in claims 29 and 30 be construed as “a digital record of a pattern created on a tactile input device of the health tracker.” PHT’s proposed construction -- which is supported by the plain language of the claim -- covers any embodiment where information is stored in the data logger (digital record) based on information input through the tactile input device. For example, PHT’s construction would cover a system in which the patient could “type” words into the data logger on a digital image of a keyboard using a stylus, or a system in which the patient can use a stylus to indicate where he or she was feeling pain.

The construction proposed by CRF and invivodata would apparently limit claim 29 to pictorial representations of the *actual handwriting*, limitations that are unjustified by the specification or the prosecution history.

The '985 patent describes a portion of the health tracker -- referred to as a “tactile input device” in claim 29 -- such as a pad or portion of the screen on the data logger, that senses a pattern created when the tactile input device is touched. For example, Figure 20A of the '985 patent shows portions of the screen 250 and 252 on the

data logger 106 on which the patient may write short notes to the doctor or sign his or her name, respectively. The specification states:

Shown in FIG. 20A is a message screen of the subjective data logger in which a space 250 is provided where the patient may write a message to a person who reviews his or her database records, such as a reviewing physician. *In the preferred embodiment, the message is transmitted as bit-mapped data, such that . . . when displayed by the recipient, it appears in the handwriting of the patient.* Although software is available which could be used to convert the message into characters, the handwriting itself may be of use to a reviewing physician in assessing the patient's medical condition and in establishing authenticity of the record. (Col. 26, ll. 44-55, emphasis added.)

The specification is clear, therefore, in stating that it is only the *preferred* embodiment in which the “digitized representation of the detected writing” appears in the handwriting of the patient.⁷

The Court should adopt PHT's proposed construction and reject the overly narrow interpretation of CRF and invivodata.

5. **“Data Transmission Device of the Portable Unit”**

Claim 34 of the '985 patent contains the following phrase: “*a data transmission device of the portable unit* that transmits data to the data storage location via a digital data network.” (Col. 31, ll. 28-30, emphasis added.) PHT proposes that the phrase “data transmission device of the portable unit” in claim 34 be construed as “a

⁷ The plain language of the claim makes clear that the digital record created must include actual data representing a pattern created on the tactile input device; a mere digital representation of the patient's handwriting, such as an electronic signature stamp that has not been captured by the tactile input device, would not be sufficient to satisfy the claim limitation.

component enabling connection of the portable unit to a communications network to permit transmission of data to the data storage location site without the data being processed by or accessed on an intervening computer.”

This proposed construction is similar to the construction PHT proposes for the phrase “a data transmission device capable of connecting directly to a communication network” from claim 22 (discussed in section IV.2 above). CRF and invivodata’s proposed construction for “a data transmission device of the portable unit” from claim 34 is also similar to their proposed construction for the phrase “a data transmission device capable of connecting directly to a communication network” from claim 22. That is, CRF and invivodata again assert that the claim excludes systems that include an external modem between portable unit the network. Etrials’s proposed construction is simply “a device that transmits data and is included within the portable unit.”⁸

Claim 34, unlike claim 22, does not explicitly have a requirement that the data transmission device “be capable of directly connecting” to the network. In an amendment filed March 1, 1999, however, the applicants explicitly stated that “[n]ew claim 53⁹ is also similar to Claim 1, but is limited to a data transmission device that transmits data to a remote data storage location via a digital data network.” (J.A. Ex. C at 13.) In that March 1st amendment, Claim 1 of the application was amended to specify that the handheld device included a data transmission device that is capable if connecting directly to a communications network. Thus, the “capable of connecting

⁸ The proposed construction from CRF and invivodata also incorporates a requirement that the data transmission device be “included within the portable unit.”

⁹ This claim issued as claim 34.

directly” limitation from claim 22 -- discussed extensively in section IV.2 above -- is also implicitly present in claim 34. PHT’s proposed construction of claim 34 incorporates this.

CRF and invivodata appear to agree with PHT on this issue, as their proposed interpretation of this section of claim 34 is also the same as their interpretation for “capable of connecting directly” of claim 22. The CRF/invivodata construction is correct insofar as it recognizes that the claim incorporates the “capable of directly connecting” element. But for the reasons discussed in detail in section IV.2 above, the CRF/invivodata construction wrongly construes the meaning of that limitation, by excluding the preferred embodiment (a system using an external modem) from its coverage. The CRF/invivodata construction should therefore be rejected.

Etrials’s proposed interpretation fares no better. It does not require that the data transmission device be capable of “directly connecting” the data logger to digital data network. This construction is at odds with both the prosecution history and the basic nature of the claimed invention and should be rejected.

6. “Digital Data Network”

Claim 34 recites: “a data transmission device of the portable unit that transmits data to the data storage location via a ***digital data network.***” (Col. 31, ll. 28-30.) “Digital data network” is also used in claims 36 and 37. (Col. 31, ll. 37-41.) The phrase “digital data network” in claims 34, 36, and 37 should be construed as “a network capable of transmitting digital data.”

Defendants' proposed construction is similar to PHT's construction, except that it excludes a telephone network from the definition of a "digital data network." Such a construction has no basis and should be rejected.

The '985 patent describes transmitting information from the health tracker to a central database using various types of networks. (*E.g.*, Col. 5, ll. 21-32.) Telephone networks can be digital data networks. For example, telephone communications can be carried over computer networks using a voice over Internet protocol (VoIP) system, which converts standard telephone audio into digital data so it can be sent over a computer network such as the Internet. In addition, digital information can be transmitted over traditional telephone lines using digital subscriber line (DSL) technology. So long as the network is capable of transmitting digital data, the network is a digital data network, even if the network also is capable of transmitting telephone communications.

Moreover, the claim recites that the transmission occurs "via" a digital data network. Thus, the data need not travel exclusively over a digital data network; rather, the data merely must be transmitted "via a digital data network" en route to the data storage location (Col. 31, ll. 29-30), which means that *some* portion -- not necessarily all -- of the route must be a digital data network.

7. "Public Data Network"

Claim 36 of the '985 patent recites: "A personal health tracking system according to claim 34 wherein the digital data network comprises a *public data network*." (Col. 31, ll. 37-39.) The term "public data network" in claim 36 should be given its plain meaning and construed as "a network that can be generally accessed by the

public, such as a telephone network, a WAN available to the public, or the Internet.” In effect, “public data networks” are a subset of “digital data networks,” which makes sense in view of the dependency of claim 36 from claim 34.

CRF and invivodata propose that the term “public data network” should exclude telephone networks.¹⁰ Once again, they are wrong.

As described above in section IV.6, the term “digital data network” does not exclude telephone networks. For the same reasons, “public data network” should also not exclude telephone networks. There is no reason to exclude all telephone networks from the scope of the term “public data network,” and the proposed CRF/invivodata construction should be rejected.

8. “Connection Device”

Claim 38 of the ’985 patent recites: “A personal health tracking system according to claim 34 wherein the data transmission device comprises a connection device that facilitates connection to the data network.” (Col. 31, ll. 42-45.) PHT proposes that this claim be construed as requiring that the data transmission device include “a component that enables or makes easier a connection between the portable unit and the data network.”

The ’985 patent specification states that the patient can periodically “[connect] the data logger **106** to modem **110** or another data transfer device which transfers the data to the database **102** using a known data transfer protocol.” (Col. 26,

¹⁰ Etrials has not proposed a construction for this claim.

ll. 34-37.) Neither the claim nor the specification limits the connection device to the modem or data transfer device itself. Instead, the connection device can be any device that facilitates the connection between the data logger and the modem or data transfer device. For example, the connection device can be a port associated with the telecommunications driver that permits the telecommunications driver to connect to and control an external modem or data transfer device. Nor is the claim limited to a single device that both connects to the data network and transfers data to the database. Nor does the specification state that the connection device and the device transferring the data to the database must be combined in a single device. Therefore, the connection device can be any component that enables or makes easier a connection between the portable unit and the data network.

9. **“Modem that is Connectable Directly to a Public Telephone Network”**

Claim 39 of the '985 patent recites: “A personal health tracking system according to claim 38 wherein the connection device comprises a modem that is connectable directly to a public telephone network.” (Col. 31, ll. 46-48.) PHT proposes that this claim be construed as requiring that the connection device include “a modem that can connect directly¹¹ to a telephone network that can be accessed by the public.”

The construction proposed by CRF and invivodata would exclude the presence of a modem between the data transmission device and the network.

¹¹ As discussed above in Section IV.2, “connect directly” means the data is sent from the unit to the communications network without being processed by or accessed on an intervening computer.

The '985 patent states: "In the present embodiment, the modem **110** directly connects via telephone to one of the computers that support the database **102**." (Col. 5, ll. 24-27.) In addition, during the prosecution of the application that led to the '985 patent, the applicants explained that:

[T]he handheld unit may be coupled directly to a communication network to allow direct transmission of collected data to a destination site. For example, the handheld unit may have a modem that is simply plugged into a telephone jack. (J.A. Ex. C at 11.)

The applicants did not place further limitations on the term "directly," which should be construed in accordance with its ordinary meaning. No additional limitations to the term "directly," such as the prohibition of a separate unit between the connection device and the network, should be added. Indeed, the prosecution history implies the existence of a separate unit between the modem and the telephone jack, such as a cable with the appropriate connectors to connect the modem to the telephone jack. In addition, as discussed in Section IV.2 above, the preferred embodiments described in the specification have an external modem. Accordingly, the claim should be construed as requiring that the connection device include "a modem that can connect directly to a telephone network that can be accessed by the public."

10. "Connectable Directly to a Local Data Network Access Connection"

Claim 40 of the '985 patent recites: "A personal health tracking system according to claim 38 wherein the connection device is connectable directly to a local data network access connection." (Col. 32, ll. 1-3.) PHT proposes that this claim be

construed as requiring that the connection device be able to “connect directly”¹² to a local point of access for a data network, such as an Ethernet port.”

The specification describes that, in addition to connecting via telephone, “the modem may connect to a local network access computer and transmit data to the database via the network connection.” (Col. 5, ll. 27-29.) In addition, during the prosecution of the application that led to the ’985 patent, the applicants explained that “the handheld unit may be coupled directly to a communication network to allow direct transmission of collected data to a destination site.” (J.A. Ex. C at 11.) The applicants did not place further limitations on the term “directly,” which should be construed in accordance with its ordinary meaning. No additional limitations to the term “directly,” such as the prohibition of a separate unit between the connection device and the network, should be added. Accordingly, the claim should be construed as requiring that the connection device be able to “connect directly to a local point of access for a data network, such as an Ethernet port.”

¹²As discussed above in Section IV.2, “connect directly” means the data is sent from the unit to the communications network without being processed by or accessed on an intervening computer.

V. **CONCLUSION**

For the reasons stated above, PHT requests that the claim language set out in this brief be construed in the manner proposed by PHT in the Joint Claim Chart.

Respectfully submitted,

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CERTIFICATE OF SERVICE

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